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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION

ZYDUS WORLDWIDE DMCC, Plaintiff, v. TEVA API INC., Defendant.	No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

For its Complaint against Teva API Inc. ("TAPI"), plaintiff Zydus Worldwide DMCC ("Zydus") alleges as follows:

NATURE OF THE ACTION

1. This action arises from TAPI's repudiation of promises it made to induce Zydus to purchase assets related to the manufacture and sale of generic rotigotine pharmaceutical

products from TAPI's parent, Teva Pharmaceutical Industries Ltd. ("Teva"). Teva was required to divest itself of these assets because of the U.S. Federal Trade Commission's ("FTC") concern that continued ownership would be anticompetitive. Zydus paid Teva a substantial purchase price to acquire the divested assets, relying on a binding letter of intent from TAPI (the "LOI") promising that TAPI would supply Zydus with the active pharmaceutical ingredient ("API")—known as Form I rotigotine—needed to manufacture and sell the generic rotigotine pharmaceutical products, for up to seven years at prescribed prices.

2. Access to the supply of Form I rotigotine was a critical prerequisite for this deal. The Abbreviated New Drug Application ("ANDA") for the generic rotigotine pharmaceutical products purchased by Zydus specified that the products would be manufactured using Form I rotigotine manufactured by TAPI. Without a reliable supply of the Form I rotigotine, Zydus could not obtain regulatory approval from the Food and Drug Administration ("FDA") to make or sell the rotigotine pharmaceutical products it had purchased. If TAPI did not supply Form I rotigotine, Zydus's acquisition would lose its value entirely.

3. TAPI has repudiated its obligation to supply Form I rotigotine, based on the claim that it can no longer supply Form I rotigotine to Zydus. Any production issues related to TAPI's supply of Form I rotigotine are within the control of TAPI, and, on information and belief, TAPI could reasonably take steps to restore its ability to supply Form I rotigotine. TAPI has chosen not to do so. Its parent, Teva, has pocketed the significant purchase price paid by Zydus, and TAPI would now like to walk away from this transaction with no further obligations, leaving Zydus with an acquisition of assets that it cannot use.

4. As set forth below, this suit seeks to recover from TAPI the extensive losses Zydus has suffered as a result of its failure to provide the promised supply of Form I rotigotine.

In addition (or in the alternative), it seeks specific performance to require TAPI to supply the promised Form I rotigotine.

PARTIES

5. Zydus is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeirah Lakes Towers, Dubai, United Arab Emirates.

6. On information and belief, TAPI is a corporation organized under the laws of New Jersey, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. TAPI is an affiliate of Teva and manufactures the Form I rotigotine at issue in this action.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a)(2) because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between a citizen of a State and a citizen of a foreign state (that is not admitted for permanent residence in the United States and domiciled in the same State).

8. Venue is proper in this judicial district under 28 U.S.C. § 1391 because defendant TAPI resides within this judicial district.

FACTUAL BACKGROUND

The Rotigotine Product Line

9. Rotigotine drug products are currently sold in the United States under the brand name Neupro®. Teva developed a line of generic rotigotine products, which includes transdermal patches in strengths of 1 mg/24 hours; 2 mg/24 hours; 3 mg/24 hours; 4 mg/24 hours; 6 mg/24 hours; and 8 mg/24 hours. Teva filed an Abbreviated New Drug Application to cover these products (the "Rotigotine ANDA"). The Rotigotine ANDA relies on New Drug

Application ("NDA") No. 021829 for Neupro® (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours and 8 mg/24 hours rotigotine transdermal system) held by UCB, Inc. as the Reference Listed Drug.

10. The Rotigotine ANDA specifies that the products manufactured under the ANDA must be manufactured using Form I rotigotine supplied by TAPI.

Teva Acquires Allergan and the FTC Requires Divestiture of Rotigotine Products

11. On or about July 26, 2015, Teva announced that it would acquire the generic drug business of Allergan plc ("Allergan"). After the FTC raised concerns that the acquisition could be anticompetitive, the FTC and Teva negotiated for Teva to divest certain assets.

12. Among the assets to be divested by Teva were the "Rotigotine Product Assets," consisting of Teva's rights, title, and interest in and to all assets related to Teva's business in the United States related to what the FTC defined as the "Rotigotine Products." The "Rotigotine Products" are rotigotine transdermal patches in strengths of 1 mg/24 hours; 2 mg/24 hours; 3 mg/24 hours; 4 mg/24 hours; 6 mg/24 hours; and 8 mg/24 hours that were the subject of the Rotigotine ANDA, which relies on NDA No. 021829 for Neupro® as the Reference Listed Drug.

13. Teva proposed to divest the Rotigotine Product Assets by selling them to Zydus, which would own the associated ANDA and take over the eventual sale, following FDA approval, of the Rotigotine Products in the United States. Teva and Zydus entered into an Asset Purchase Agreement (the "APA"), dated as of June 16, 2016, under which Teva agreed to sell and assign Teva's Rotigotine Product Assets (including the Rotigotine ANDA) to Zydus. Teva sold and assigned the Rotigotine Product Assets to Zydus on or about August 3, 2016.

TAPI Issues a Binding Letter of Intent to Supply the API

14. Teva's subsidiary TAPI produces the API, Form I rotigotine, at its facility located in Croatia. The ANDA specifies TAPI as the source for Form I rotigotine. Access to sufficient

supplies of Form I rotigotine from TAPI is necessary for Zydus to obtain FDA approval to manufacture and sell the Rotigotine Products.

15. For this reason, TAPI's binding commitment to supply the required amounts of Form I rotigotine at commercially reasonable prices was critical to Zydus's willingness to proceed with the acquisition of the Rotigotine Product Assets. TAPI committed to provide Form I rotigotine and memorialized its commitment in a binding LOI, dated May 24, 2016. Without this binding commitment, Zydus would not have gone forward with the acquisition.

16. The LOI committed TAPI to supply commercial quantities of Form I rotigotine at a price of $37,500/kg for the initial three-year term. After the initial term, the term would automatically be extended for two successive two-year renewal terms unless Zydus gave written notice of non-renewal. After the initial term, TAPI was permitted to increase the price on an annual basis based on increases in the appropriate Producer Price Index.

17. The LOI provided for the parties to negotiate a definitive supply agreement. However, it expressly stated that, notwithstanding the anticipated definitive agreement, "this LOI represents a binding commitment with respect to the supply terms included herein." No further definitive supply agreement has been negotiated as TAPI has repudiated its obligation to supply the Form I rotigotine as discussed below.

TAPI Repudiates Its Supply Obligations

18. Zydus has now been informed that TAPI will not supply Form I rotigotine to Zydus, allegedly because TAPI is no longer able to produce Form I rotigotine.

19. On information and belief, Teva could reasonably restore its ability to produce and supply Form I rotigotine. Moreover, TAPI's purported inability to supply Form I rotigotine is not due to circumstances beyond its control or without its fault.

20. TAPI has breached the LOI by refusing to supply Form I rotigotine. Zydus relied on TAPI's promise to provide a multi-year supply of the required Form I rotigotine when it proceeded with the acquisition of Teva's Rotigotine Assets and invested millions of dollars to seek FDA approval of the ANDA and for related patent litigation. Without TAPI's promise and binding LOI, Zydus would not have acquired Teva's Rotigotine Assets. TAPI is liable for damages arising from its breach of its promise and binding contractual obligation.

Zydus Suffers Significant Losses and Damages

21. TAPI's breach of its promises and the LOI have caused and will cause substantial compensable losses and damages to Zydus. These include, without limitation, the following:

a. Zydus incurred substantial expenses acquiring the Rotigotine Product Assets (including the Rotigotine ANDA) from Teva. These expenses include the purchase price for the Rotigotine Product Assets, as well as legal fees, expenses, taxes, and other transaction costs. Zydus invested in this acquisition in reliance on TAPI's promises and binding LOI. Without a supplier for the required Form I rotigotine, the value of Zydus's acquisition is substantially or completely impaired.

b. Following its purchase of Teva's Rotigotine Assets, Zydus expended significant legal fees and other expenses in patent litigation and seeking FDA approval of the ANDA to manufacture and sell the product. Zydus would not have incurred these expenses if not for TAPI's promise and agreement to provide Form I rotigotine. The value of Zydus's investment in FDA approval has been lost due to TAPI's repudiation of the LOI and its promises.

c. Zydus has lost its ability to obtain approval for and sell the Rotigotine Products and will therefore lose future profits as a result of TAPI's repudiation of its promises.

COUNT I
Breach of the Binding Letter of Intent

22. Zydus incorporates by reference the above paragraphs 1-21 and restates those paragraphs as if fully set forth in this cause of action.

23. The LOI is a binding and enforceable contract between Zydus and TAPI requiring TAPI to provide quantities of the API, Form I rotigotine, that are reasonably sufficient to supply the territory.

24. Zydus has fulfilled its obligations under the LOI.

25. TAPI has repudiated its obligation to supply the API, Form I rotigotine, and has thereby breached its obligations under the LOI.

26. Zydus has incurred significant losses, as detailed herein, as a result of TAPI's breach of the LOI.

COUNT II
Specific Performance of the LOI

27. Zydus incorporates by reference the above paragraphs 1-21 and restates those paragraphs as if fully set forth in this cause of action.

28. The LOI is a binding and enforceable contract between Zydus and TAPI requiring TAPI to provide reasonably sufficient quantities of the API, Form I rotigotine.

29. Zydus has fulfilled its obligations under the LOI.

30. TAPI has repudiated its obligation to supply the API, Form I rotigotine, and has thereby breached its obligations under the LOI.

31. This Court can readily determine from the LOI, with reasonable certainty, the duties of each party and the conditions under which performance is due. On information and belief, TAPI has the ability to produce the API, Form I rotigotine. An order compelling performance of the contract is appropriate and will not be harsh or oppressive.

32. Money damages are not adequate to protect Zydus's expectation interests.

33. An order requiring specific performance of Teva's obligation to supply the API, Form I rotigotine, is appropriate and will not result in inequity to Teva or conflict with public policy.

COUNT III
Promissory Estoppel
(In the Alternative)

34. Zydus incorporates by reference the above paragraphs 1-21 and restates those paragraphs as if fully set forth in this cause of action.

35. Zydus pleads this claim for promissory estoppel in the alternative to its breach of contract and specific performance claims.

36. The LOI expresses a clear and definite promise by TAPI to supply commercial quantities of the API, Form I rotigotine, at a definite price for an initial three-year term, automatically extended for two successive 2-year renewal terms.

37. TAPI expected and intended that Zydus would rely on its promise in undertaking to acquire the Rotigotine Assets.

38. Zydus reasonably relied on TAPI's promise in proceeding with the acquisition, seeking FDA approval, defending a patent suit, and other actions. Without TAPI's commitment to supply the API, Form I rotigotine, Zydus would not have gone forward with the acquisition, nor would it have expended resources seeking FDA approval and defending the patent suit.

39. TAPI repudiated and breached its promise.

40. As described herein, Zydus has suffered substantial and definite detriment as a result of TAPI's breach of its promise.

41. In the event that the Court determines the LOI is not an enforceable contract requiring TAPI to supply the API, Form I rotigotine, Zydus is entitled to recover under the doctrine of promissory estoppel.

RELIEF REQUESTED

WHEREFORE, Zydus requests that this Court:

A. Enter judgment for Zydus on all counts of this complaint;

B. Award Zydus damages in an amount to be proven at trial;

C. Order specific performance by TAPI of the Letter of Intent;

D. Award Zydus the costs and expenses of this litigation, including reasonable attorneys' fees and costs of suit; and

D. Award Zydus such other and further relief as this Court deems just and proper.

JURY DEMAND

Zydus demands a trial by jury on all claims so triable.

Dated: August 22, 2019

Respectfully submitted,

By: s/ *Joseph N. Froehlich*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

The matter in controversy in this action is, in part, the subject of another action being filed concurrently in the Supreme Court of the State of New York, County of New York, entitled *Zydus Worldwide DMCC v. Teva Pharmaceuticals Industries Ltd*. The New York action is brought against a different defendant that is not a party to this case and is based in large part on a separate contractual instrument that is not at issue in this case.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: August 22, 2019

s/ *Joseph N. Froehlich*